DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NEC Display Solutions, Ltd.
% Mr. Tony Hsu
Project Engineer
Prodigy Technology Consultant Co., Ltd.
1F, No. 181, Sec.2, Wunhua 1st Road
Linkuo, New Taipei City, 24447
TAIWAN

December 10, 2014

Re: K142951
Trade/Device Name: MD210C3 21.3" Diagnostic Imaging LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: October 9, 2014
Received: October 16, 2014

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142951

Device Name
Medical Display, MD210C3

Indications for Use *(Describe)*
The MD210C3 color display is intended to be used for displaying and
viewing of digital images for diagnosis by trained physicians.
To guarantee the display performance as specified, it must only be used for in
Conjunction with NEC approved display controllers.
MD210C3 cannot be used for a life-support system.
This device must not be used in digital mammography.
This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary of Safety and Effectiveness

As required by 807.92

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Mr. Satoru Kotani
Manager
NEC Display Solutions Ltd.
4-28, Mita 1-chome, Minato-ku, Tokyo, Japan
Ph: +81-465-85-2384
Fax: +81-465-85-2393

2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

19 September 2014

4. DEVICE NAME

Trade Name:	MD210C3 21.3” Diagnostic Imaging LCD monitor
Model Name:	MD210C3
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)
Product Code:	PGY

4. PREDICATE DEVICE

MD211C3 3MP Color LCD Monitor by NEC Display Solutions Ltd. (K130770)

5. DEVICE DESCRIPTION

Medical Display, MD210C3 is a 21.3” Color LCD monitor that displays image for medical use. It provides 3 mega pixel (2048*1536) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDED USE

The MD210C3 color display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used in conjunction with NEC approved display controllers.

MD210C3 cannot be used for a life-support system.

This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

7. SE Comparison Table:

Comparison tables between MD211C3 & MD210C3

Items	**MD211C3**	**MD210C3**
510(k) Number	K130770	
Panel Size and Type	21.3" TFT Color LCD Monitor	21.3" TFT Color LCD Monitor
Pixel Pitch	0.212 mm x 0.212mm	0.212 mm x 0.212mm
Display Color	1,073,741,824	1,073,741,824
Viewing Angles (^{o})	H:176, V:176	H:176, V:176
Scanning Frequency (H, V)	31.5-94.8, 126.3kHz , 30, 50-85 Hz	31.5-94.8, 126.3kHz , 30, 50-85 Hz
Native Resolutions	2048X1536 (Landscape) 1536X2048 (Portrait)	2048X1536 (Landscape) 1536X2048 (Portrait)
Brightness	400 cd/m2 calibrated, 800 cd/m^2 Max.	400 cd/m2 calibrated, 800 cd/m^2 Max.
Contrast Ratio	1400 : 1 (typical)	1400 : 1 (typical)
DOT Clock	188 MHz	214.3 MHz
Input Signals	Two connectors: one DVI-D, one display port (Display port comply with standard V1.1a, applicable to HDCP	Two connectors: one DVI-D, one display port (Display port comply with standard V1.1a, applicable to HDCP
Input Terminals	DVI-D, Display port	DVI-D, Display port
USB (option) / Standard	No	No

Active Display Size (H x V)	Landscape: 433mmX325mm Portrait: 325X433mm	Landscape: 433mmX325mm Portrait: 325X433mm
Viewable Image Size	540 mm (diagonal)	540 mm (diagonal)
Luminance Calibration	Software	Software
Default Gamma	1.8,2.0,2.2 DICOM part 14	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Input Rating	1.1-0.4A	1.1-0.44A
Power Save Mode	<2W	<2W
Dimensions **(W x H x D)**	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape:434.3.6-584.3mm Portrait:487.4-637.4mm D: 306 mm	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape:434.3.6-584.3mm Portrait:487.4-637.4mm D: 306 mm
NET Weight	11.8 kg	11.8 kg
Intended of use	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1certified equipment
Certifications & Standards	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM

Modification	**Testing**
Change D/D board A to D/D board B	Low voltage reliability
Change input rating from 1.1- 0.4A to 1.1 – 0.44A	1) Power input test 2) Humidity preconditioning treatment 3) Temperature test 4) Leakage current test

Dot clock from 188 MHz to 214.3 MHz	--

Display Testing:

- Display Reflection
- Luminance Response
- Luminance Uniformity
- Display Resolution
- Display Noise
- Veiling Glare
- Display Chromaticity
- Miscellaneous Tests

Summary: Test results showed minor differences between MD210C3 and MD211C3, however these differences are minor and were within the acceptable range of DICOM part 14.

CONCLUSION

1. MD210C3 is identical to MD211C3 except for different D/D board of LED backlight, change current rating from 1.1-0.4A to 1.1 - 0.44A, dot clock has also improved from 188 MHZ to 214.3 MHZ.
2. These two devices have the same target population of trained practitioner in hospital; it shares the same design, same performance and is the same in radiation safety (EN60601-1-2), mechanical safety, electrical safety (AAMI/ES 60601-1) human factors and DICOM conformance. It use similar material, and have same compatibility with environment and other device. The SE Comparison Table compares the principal characteristics of two devices. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to MD211C3 by NEC Display Solutions Ltd. (K130770)